

Snapshots of current global vaccine manufacturing capacity

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Marie-Paule Kieny



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Vaccine production, 30 years ago...

- EPI vaccines were mainly produced by local manufacturers in many countries by the public sector (Europe/Asia/Latin America) Small participation of the pharmaceutical industry
- Public Institutions or Foundations (e.g. Institute Pasteur, Merieux Biological Institute, CSL, Sclavo, SSI, SBL) and some of them supplying UNICEF
- Small scale production, less complex technology, fewer regulations
- Lower R&D costs (i.e. clinical trials)
- Lower liability costs



Vaccine production, 10 years ago...

- EPI vaccines & antitoxins were produced locally by 61 countries (Latin America, Africa, Asia and East Europe)
- Producing countries declined from 61 in 1990 to 26 in 2005, possible reasons:
 - Inability to upgrade facilities for compliance with cGMP
 - Inability to innovate
- Privatization era, increasing role of private sector in vaccine production
 - In the last 10 years, decrease in number of producers and mergers of big companies (Novartis, GSK, sanofi-pasteur)

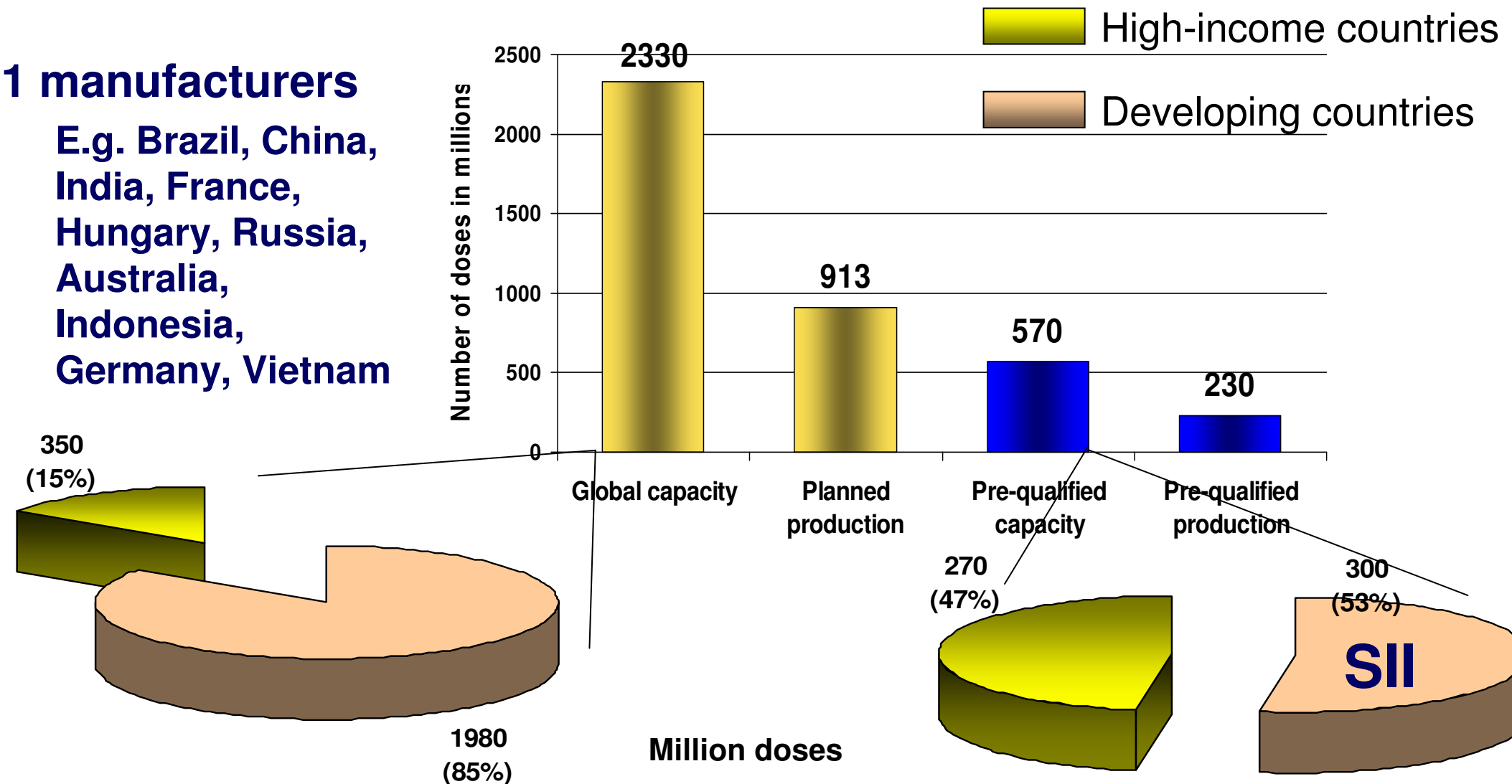


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Example: Global vaccine production-DTwP 2004

1 manufacturers

E.g. Brazil, China, India, France, Hungary, Russia, Australia, Indonesia, Germany, Vietnam



Supply to UNICEF/PAHO - 2004

SII = 75%

LG, Shantha,
Heber, KGC =
93%

GSK = 100 %

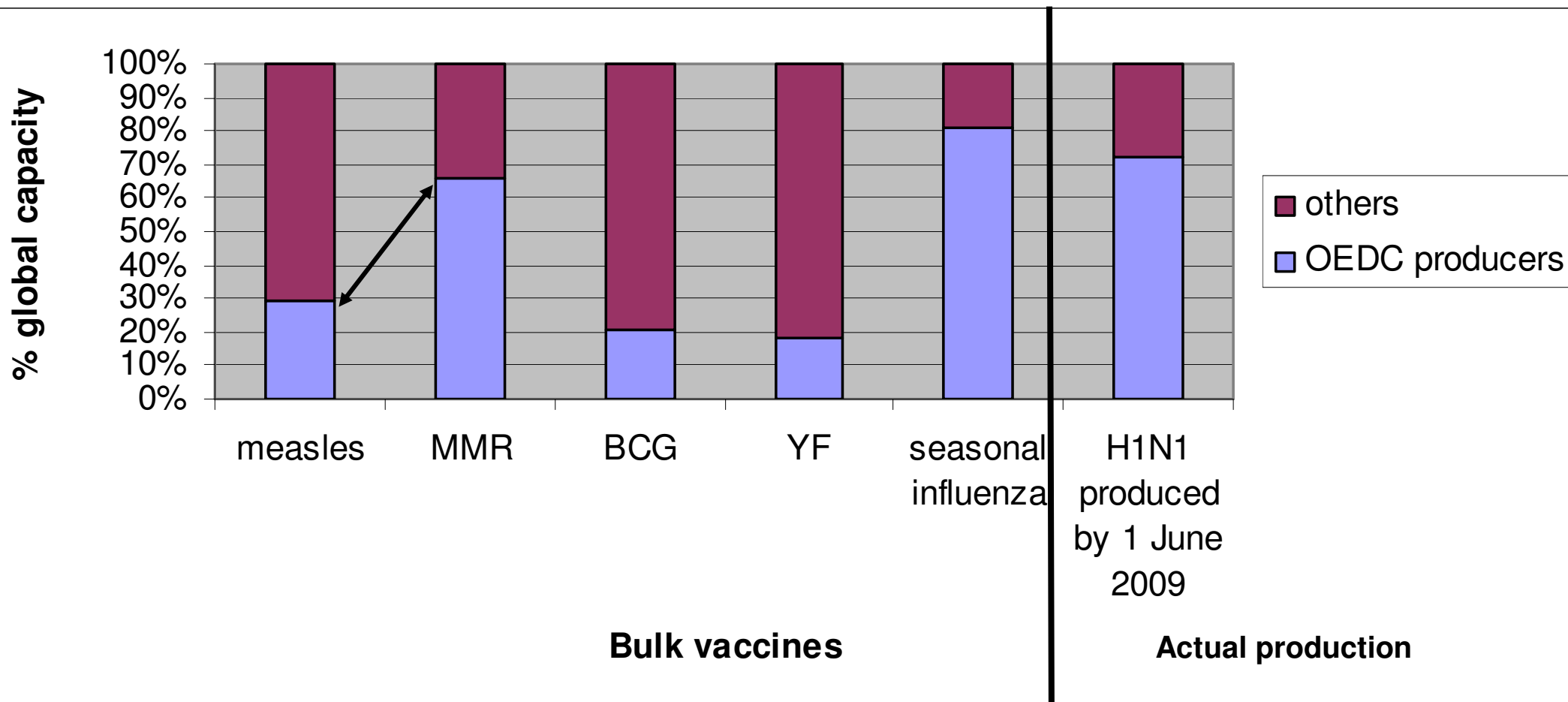


Vaccine	UNICEF (Million doses)	PAHO (Million doses)
DTwP	145	9.57
HepB	55	12.5
Hib	-	0.37
DTwP-Hib	2.5	4.6
DTwP-HepB	11.8	-
DTwP-HepB+Hib	16	8.4

Vaccine production, today...

- Basic antigens are still produced mainly in developing countries. e.g. DTwP and HepB
 - Vaccine quality issue with some producers
 - Large production capacity in China and India
- The number of producers of DPT combos in developing countries is increasing i.e. DTwP-HepB and DTwP-HepB-Hib
- New antigens are produced only in high-income countries i.e. HPV, PCV, rotavirus, but these vaccines are in the development pipeline of many DCVM
- Developing countries are becoming the major UNICEF suppliers (volume) e.g. SII, Panacea, LG

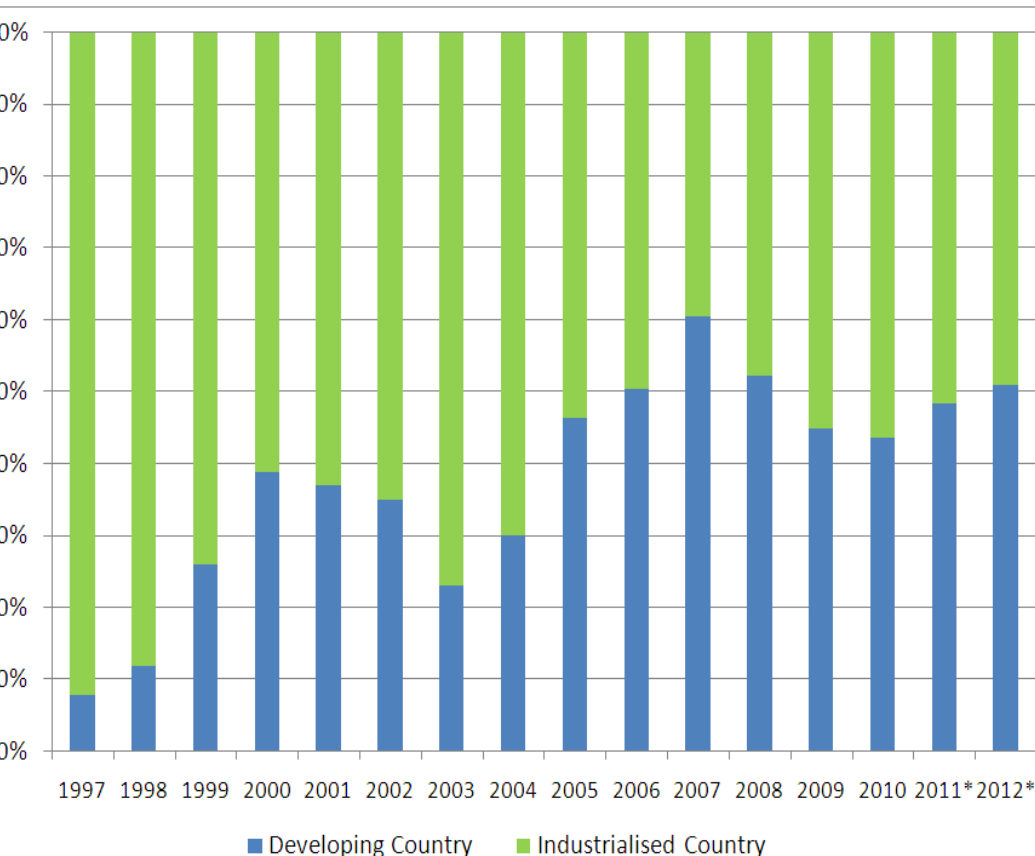
Distribution of bulk production capacity for selected vaccines



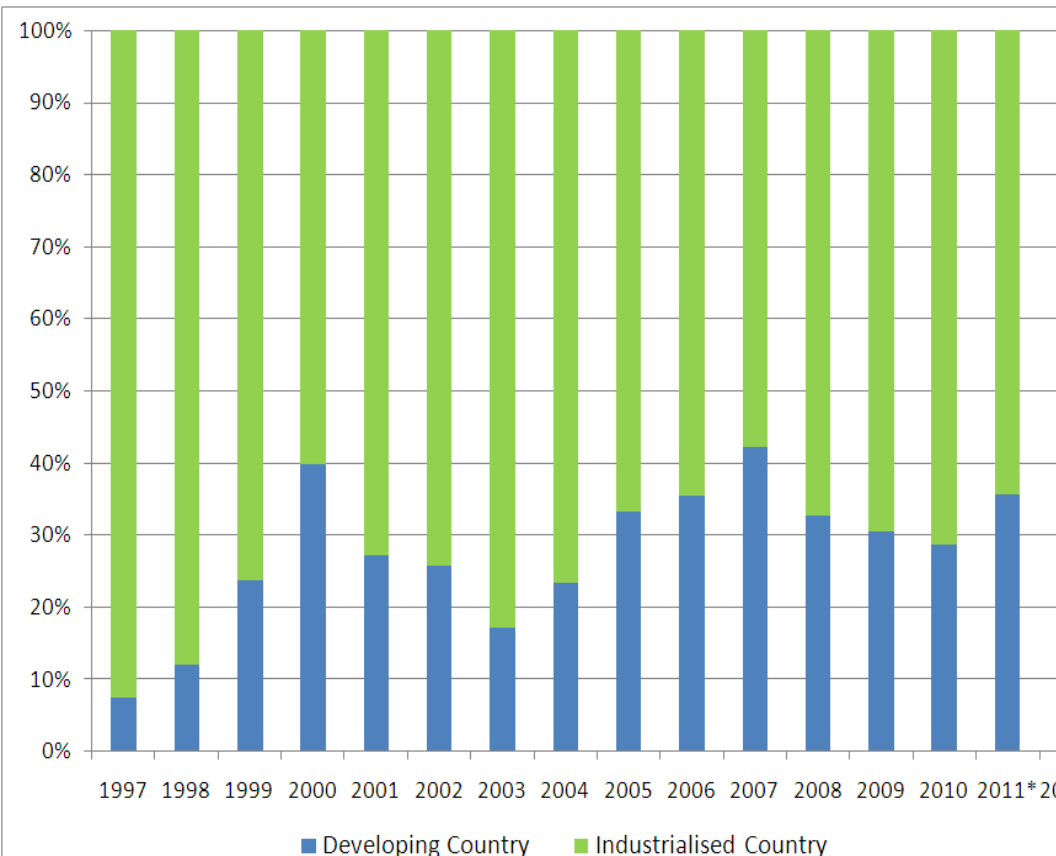
A growing portion of vaccines procured by UNICEF come from Developing Country Manufacturers

2009: 1.3 billion doses with a value of ~ \$250 million

Share by Volume



Share by Value

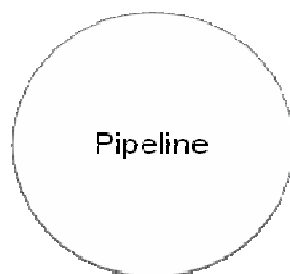


Number of
suppliers per
vaccine

Vaccine Group	Number of Manufacturers awarded in 2001-2003	Number of Manufacturers awarded in 2004-2006	Number of Manufacturers awarded in 2007-2009	Number of Manufacturers awarded in 2010-2012
DTP-HepB+Hib	1	1 => 2	2 => 4	4 => 3 => 4
DTP+Hib	0	0	1	1
DTP-HepB	1	1 => 2	3	2 => 1
YF	3	3 => 2	3	4
Measles	5	5 => 4	3	3
MMR	3	3 => 2	2	2
MR	1	1	2	2
OPV	4	5	6	6
BCG	5	4	4	4
DTP	5 => 4	4 => 3	3	3
TT	7	4	3 => 4	4 => 5
HepB	4	5	6 => 5	3
DT/Td	3	2	2/2	2/2

UNICEF contracted WHO pre-qualified vaccines suppliers over time, showing changes during the period

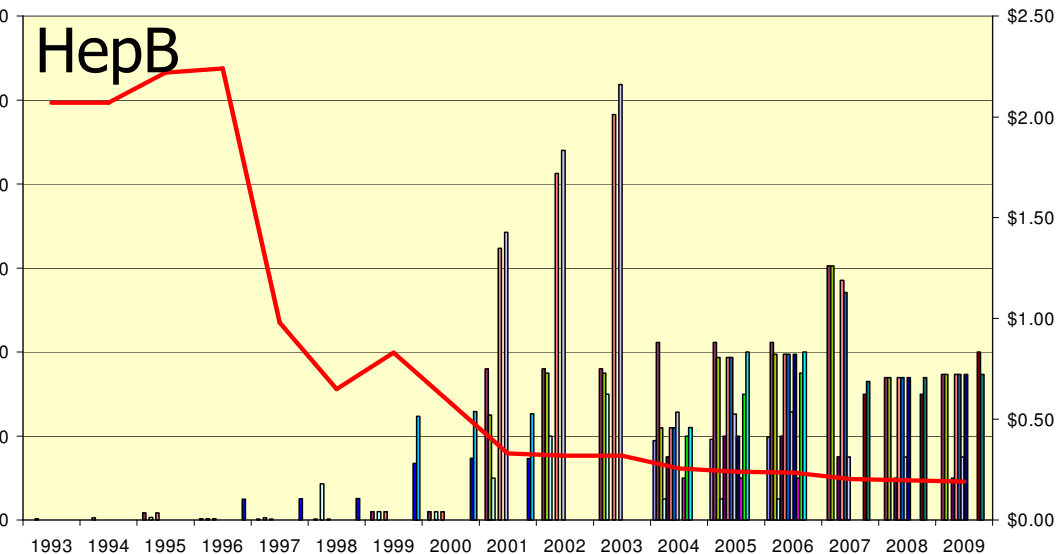
Positive trends: broadening the supply base; reducing the risk of supply interruptions; increasing competition



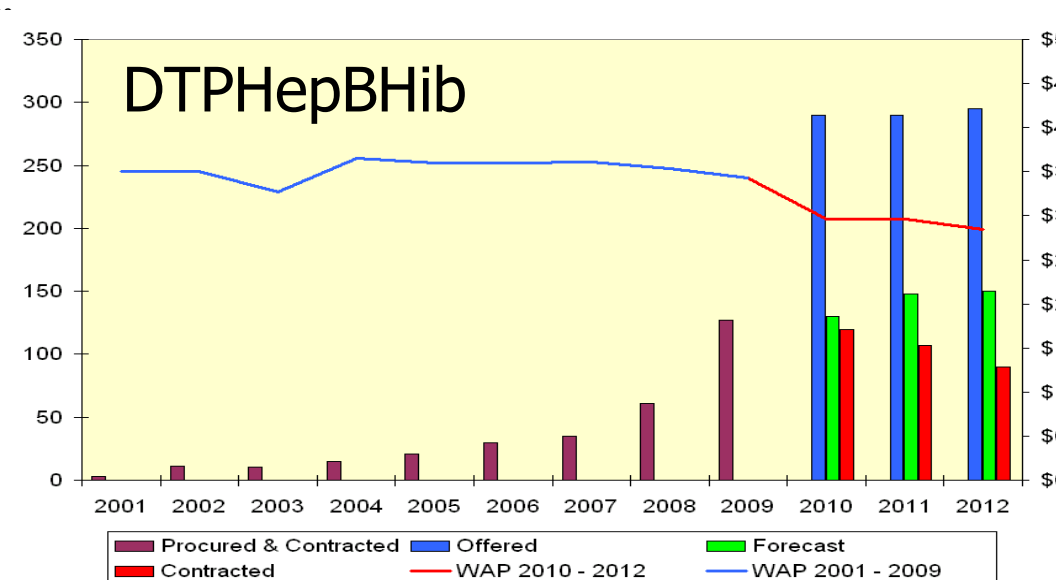
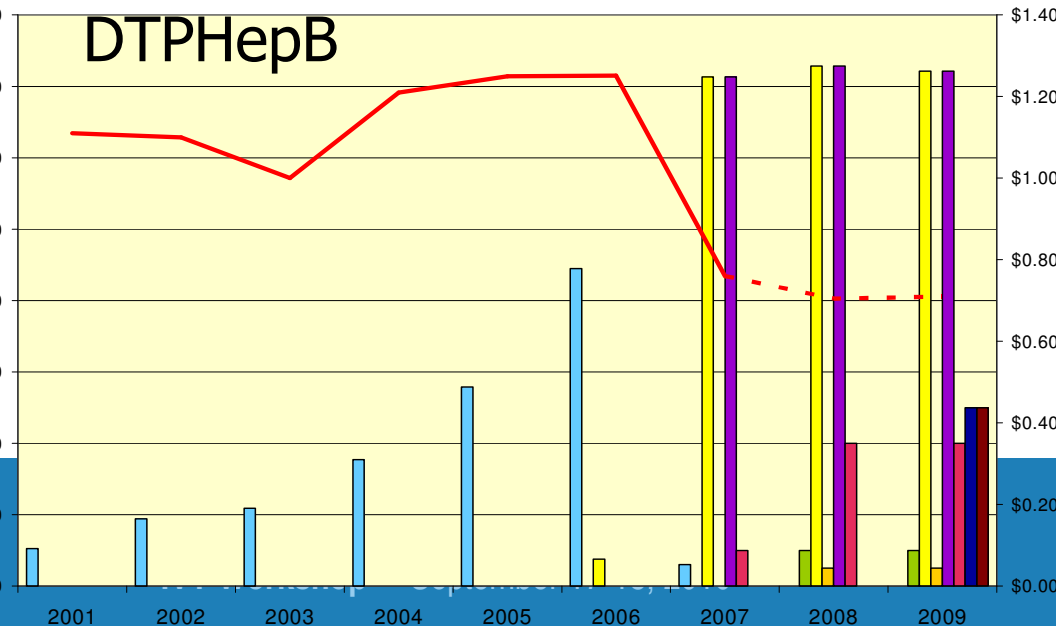
Vaccine Group	Number of Manufacturers in the pipeline in 2007-2009	Number of Manufacturers in the pipeline in 2010-2012	Number of Manufacturers in the pipeline in 2010-2012
	total	total	from Developing Countries
DTP-HepB+Hib	6	5	5
DTP+Hib	3	1	0
DTP-HepB	9	2	1
YF	1	0	0
Measles	6	5	2
MMR	1	2	1
MR	1	2	0
BCG	0	0	0
DTP	4	2	2
TT	6	2	2
HepB	4	1	1
DT	4	1	1
Td	2	2	2

Impact of number of suppliers and volume on vaccine price

HepB vaccine offered to UNICEF 1993-2009



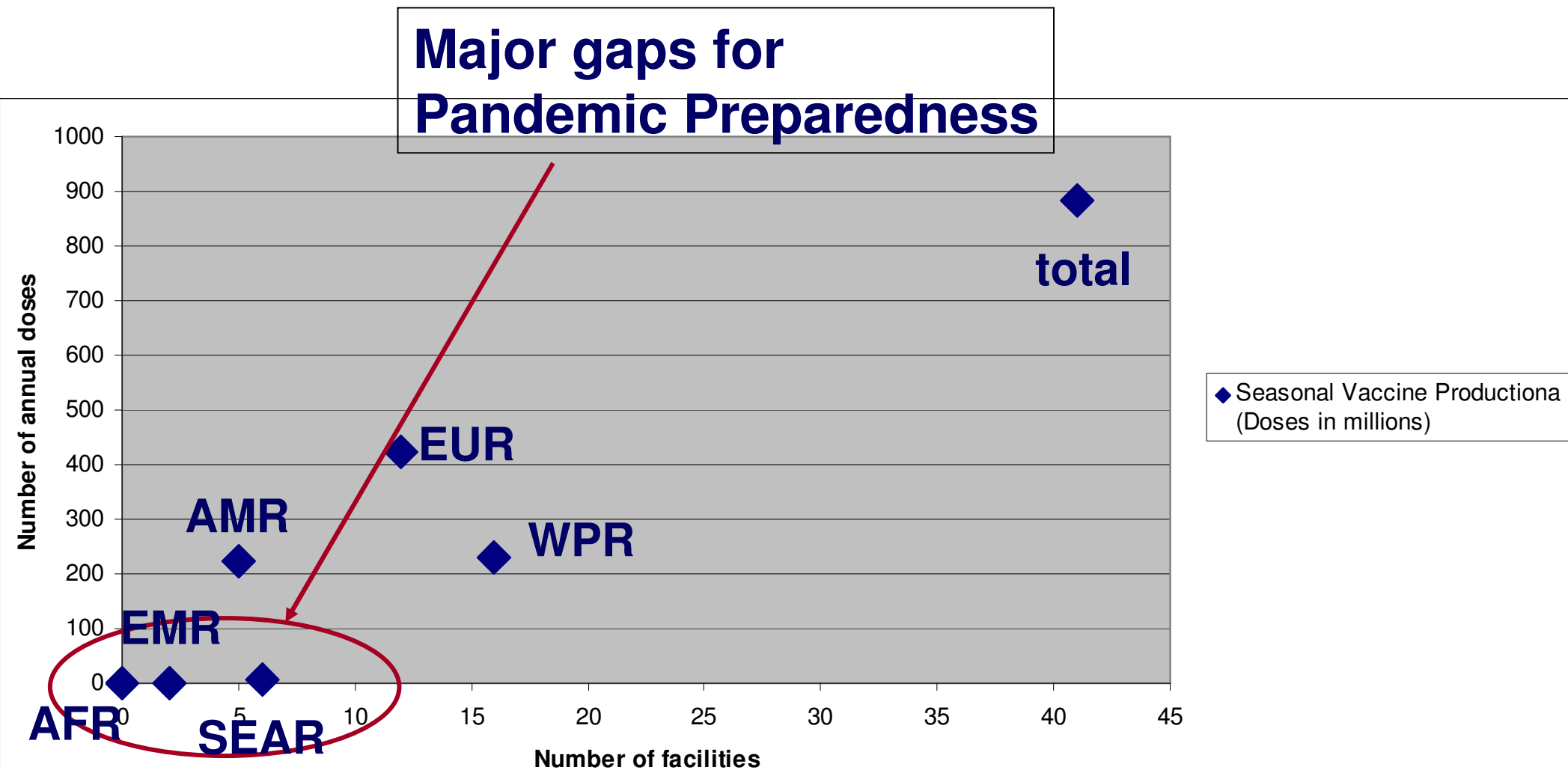
- HepB price dropped with entry of many manufacturer
- Same experience starting to be seen with DTPHepB in 2007
- For DTPHepBHib in 2010...?



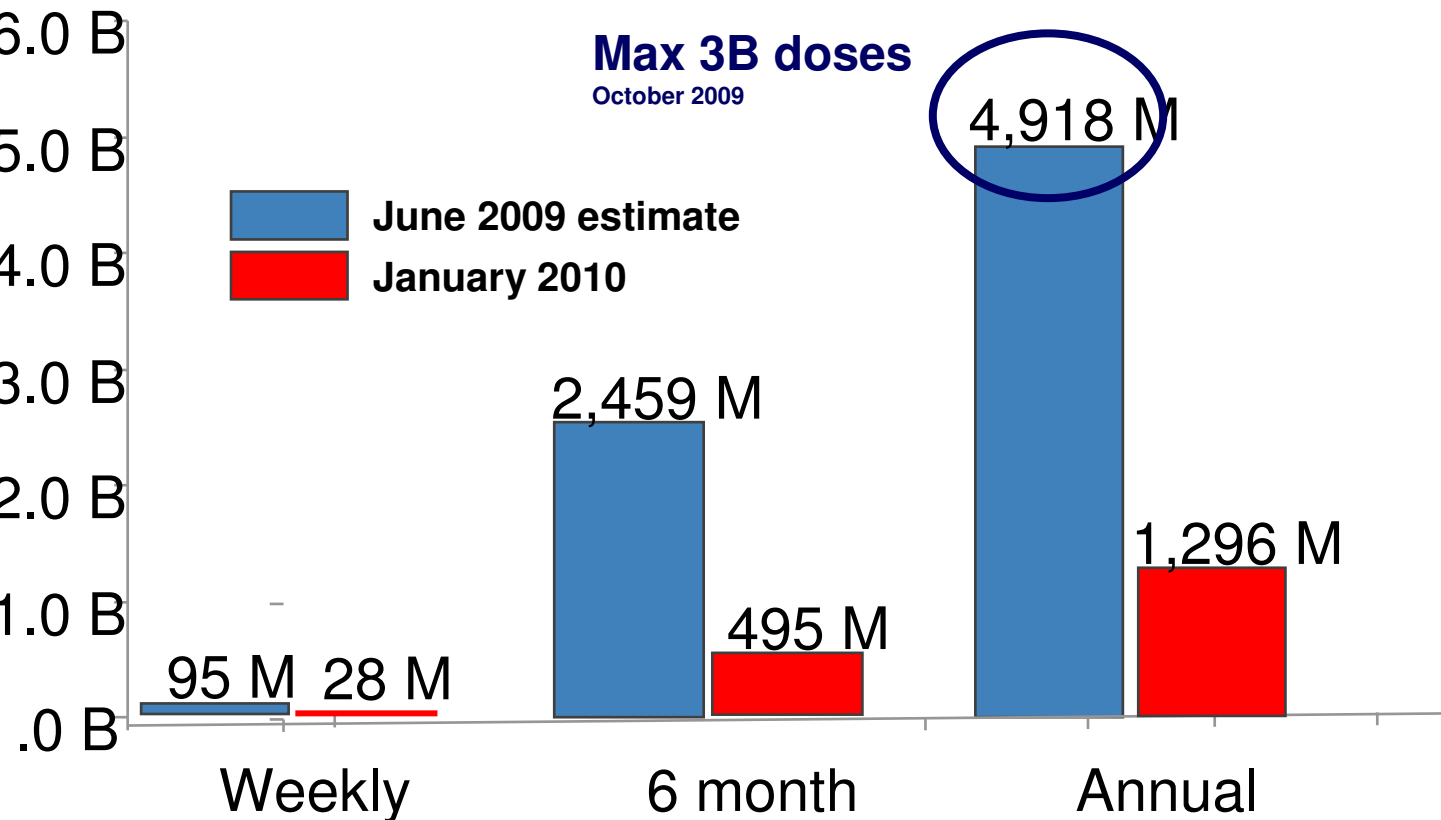
DTPHepBHib

Procured & Contracted Offered Forecast
Contracted WAP 2010 - 2012 WAP 2001 - 2009

Seasonal Vaccine Production Capacity, per WHO Region in 2009



Global pandemic (H1N1) 2009 vaccine : Planned vs actual production*



*As of 10 January 2010

June 2009 survey assumed

- 1:1 H1N1 to seasonal yields
- Most dose sparing formulation for **each** manufacturer
- Use of full production capacity

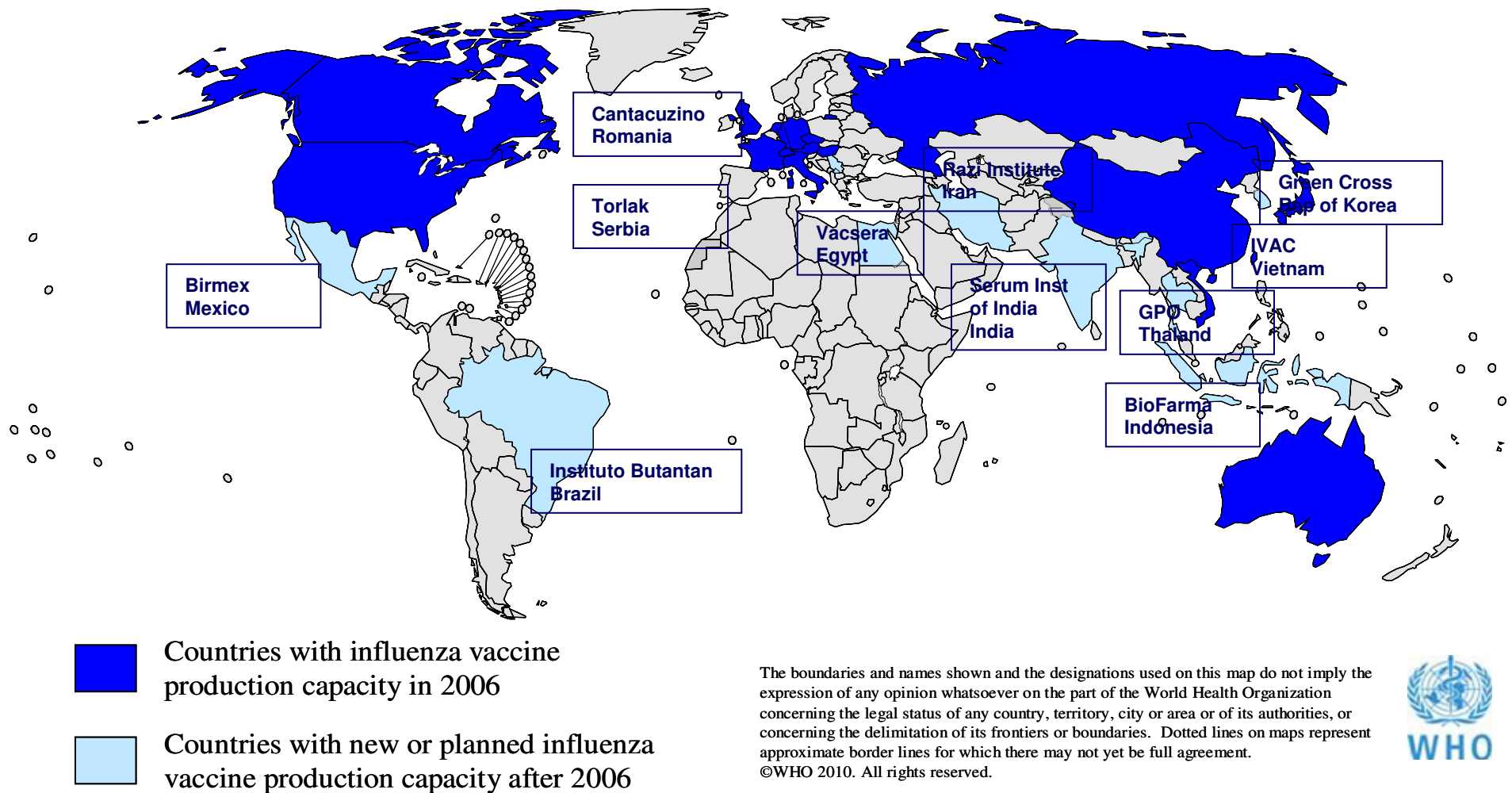
In reality

- 1:3 H1N1 to seasonal yields
- Not all manufacturers could use the most dose sparing formulation
- Production capacity was used for seasonal vaccine
- Demand collapsed in 2010



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Countries with influenza vaccine production capacity in 2006 and following implementation of the WHO Technology transfer project

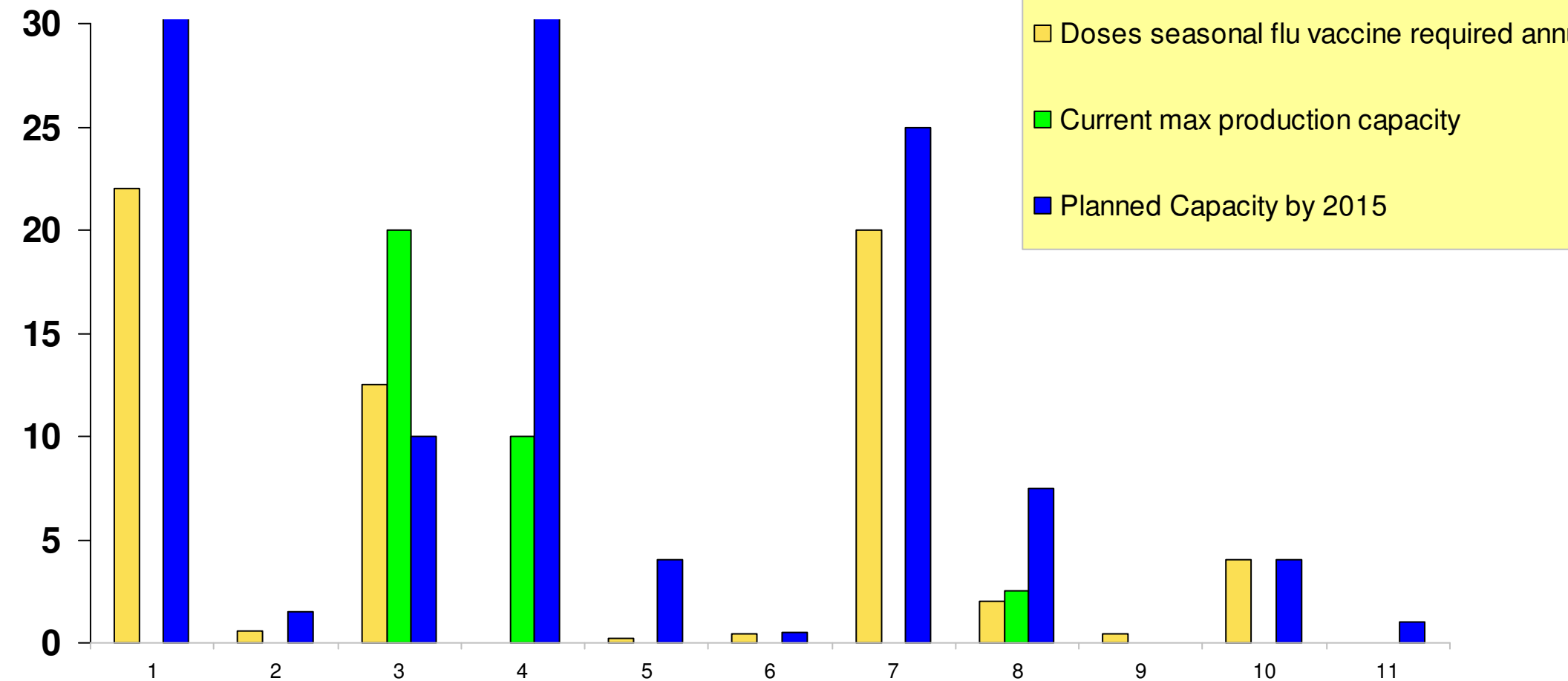


Influenza Vaccine Production Capacity by Manufacturer in Developing Countries

Doses in million

>50

110



Conclusion on global influenza vaccine production capacity

- Global influenza vaccine production capacity has increased sharply from 350 million in 2006;
- Number of pandemic A(H1N1) vaccine produced over a 6-month period was less than 500 million doses. In case of a severe pandemic, this would have allowed to immunize about 250 million of the more than 6 billion people globally with a 2-dose regimen;
- New manufacturers have been established in developing countries, which brings hopes to more adequate production capacity and equitable access in case of a future pandemic;
- Adequate production capacity is still lacking in many regions of the world, in particular in sub-Saharan Africa and Eastern Europe.



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Summary

- What we have:
 - Information about current production capacity and supply for DTwP, HepB, Hib and combos
 - Rough estimation on "emerging suppliers" with new antigens in the pipeline, R&D status, time for licensing, capacity, and production plans



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Summary

- What we do not have:
 - Reliable global production capacity, production plans & new technologies information for: meningo conj., pneumo conj., rotavirus, HPV, JEV, and others e.g. typhoid
 - Vaccine costs and prices

